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10/796,239

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Fred T. Lee JR.

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

NOTIFICATION DATE

DELIVERY MODE

02/27/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

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Applicant argues that the addition of Figure 9 does not constitute new matter. The examiner must respectfully disagree. Newly submitted Figure 9 illustrates specific configurations of the device not previously illustrated, and is therefore new matter. In addition, applicant's reliance on the figures to illustrate certain features of the invention not discussed in the disclosure further underscores that new matter is introduced by this new figure.

With regard to the art rejection, applicant asserts that Gough et al ('143) does not teach an insulative member between the two sets of electrodes therein. The examiner must respectfully disagree. Firstly, Gough et al ('143) do teach the use of an insulative sleeve, 18, as noted by applicant. Taking the totality of the disclosure of Gough et al ('143), along with the knowledge of one of ordinary skill in the art, the use of this sleeve at least along the length of the trocar at least between the two sets of antennas disclosed by Gough et al ('143), is fairly taught therein. Firstly, it is noted that Gough et al ('143) was derived from a parent application, as a continuation in part, the parent application maturing in U. S. Patent No. 5,683,384, which specifically refers to the element 14 in the drawings thereof as a "primary antenna". Clearly the conversion of this element to a "trocar" in Gough et al ('143) is intended to convey that this element is can be used for purposes other than to send or receive energy. Secondly, column 5, lines 48-55, discusses that the insulating sleeve can be positioned around the trocar and can have one or more apertures, which permit the introduction of the antennas through the trocar and the insulating sleeve. Thirdly, in the discussion of Figure 4 at column 8, lines 1-4, Gough et al ('143) discuss a configuration wherein a lesion is produces "with a minimal central core that is not ablated." Thus clearly Gough et al ('143) were aware of the ability of the ability of the trocar to sink electrical current, if it was metal, and to provide an arrangement where an insulating

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sleeve could be deployed thereon to prevent the current from heating the tissue adjacent the trocar, should that be desirable.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “support shaft having an outer surface and a distal tip, wherein the support shaft has an electrically insulated cover on the outer surface between a first and second locations, the cover extending to the distal tip of the support shaft; ... first and second wire electrode sets extensible radially from the shaft...” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

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must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Figure 9 adds new matter, because the precise configurations of the kits now shown were not previously disclosed. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

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informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed November 21, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “support shaft having an outer surface and a distal tip, wherein the support shaft has an electrically insulated cover on the outer surface between a first and second locations, the cover extending to the distal tip of the support shaft; ... first and second wire electrode sets extensible radially from the shaft...”.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 13, and 16-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on “support shaft having an outer surface and a distal tip, wherein the support shaft has an electrically insulated cover on the outer surface between a first and second locations, the cover extending to the distal tip of the support shaft; ... first and second wire electrode sets extensible radially from the shaft...”. The

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Claims 1-9, 13, and 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al ('143) in combination with Swanson et al. Gough et al ('143) teach a device as claimed except for the specific disclosure that the current is passed from one electrode set to the other and the specific frequencies claimed. Swanson et al teach using frequencies in the 1 KHz range, to which tissue has a high resistivity. It would have been obvious to the artisan or ordinary skill to employ the frequencies in the 1 KHz range, since these are frequencies to which tissue has a high resistivity, as taught by Swanson et al, and would thus produce more heating, and to configure the device to produce current flow in the axial direction when there are multiple electrodes, since this would ablate the tumor more quickly than the procedure involving rotation, discussed by Gough et al ('143), and to provide multiple sets of electrodes with the particular relative dimensions claimed, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, and to provide the insulating sleeve along at least the length of the trocar between the two sets of antenna, since this would prevent current from being grounded through the trocar, thus producing a device, kit, and method such as claimed.

Applicant's arguments filed November 21, 2007 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 1-9, 13, and 16-27 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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